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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,532	10/07/2004	Gerd Ascher	KS4255US (#90711)	8872
<div>7590 09/14/2009</div> <div>D. Peter Hochberg, Esq. D. Peter Hochberg, Co., L.P.A. 1940 East 6th Street - 6th Floor Cleveland, OH 44114</div>				
<div>EXAMINER</div> <div>CLAYTOR, DEIRDRE RENEE</div>				
<div>ART UNIT</div>		<div>PAPER NUMBER</div>		
1617				
<div>MAIL DATE</div>		<div>DELIVERY MODE</div>		
09/14/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/510,532

**Applicant(s)**

ASCHER ET AL.

**Examiner**

Renee Claytor

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 6-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/13/2009 has been entered.

Currently, claims 3 and 6-8 are pending.

### ***Response to Arguments***

Applicants have cancelled claim 5 and the 35 USC 112, first paragraph rejection over this claim is hereby withdrawn.

Applicants argue that the compounds of the present invention show activity against strains of *H. pylori*. Applicants point out that compounds that were shown to inhibit *H. pylori* activity treated peptic ulcer diseases and gastric adenocarcinoma. The above arguments are considered persuasive and the 35 USC 112, first paragraph enablement rejection is hereby withdrawn. However, upon further review the following new 35 USC 112, first paragraph scope of enablement rejection is being entered below.

Please see the following new grounds of rejection.

***Claim Rejections – 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 6-8 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for activity of three pleuromutilin compounds against five different *H. pylori* strains, does not reasonably provide enablement for the treatment of all diseases mediated by *H. pylori* with all pleuromutilins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

**1) The nature of the invention and breadth of the claims:** The claims are drawn to a method for the treatment of diseases mediated by *Helicobacter pylori* comprising administration of an effective amount of a pleuromutilin.

**2) The presence or absence of working examples and the amount of direction or guidance presented:** The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. >See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004).

The determination of a particular claimed compound in the treatment of diseases mediated by *Helicobacter pylori* requires that the compound be synthesized, formulated in a suitable dosage form and tested in a known assay that is correlated with clinical efficacy. The examples presented in the instant specification are in vitro tests that show three different pleuromutilins that have an effect on five different strains of *H. pylori*. Further, Applicants have shown that the state of the art regarding the connection between *H. pylori* and diseases such as peptic ulcer disease and gastric adenocarcinoma. However, there is no data presented in the specification indicating that all pleuromutilins will be effective in any disease associated with *H. pylori*.

**3) The state of the prior art:** A review of the literature indicates that *H. pylori* has implications in many other disease states, such as cardiovascular diseases as taught by De Luis et al. (Diabetes Care, Vol. 21, Number 7, July 1998). De Luis et al. teaches that the prevalence of heart disease is higher in patients with *H. pylori* than without (see Results). Therefore, *H. pylori* is involved in other disease states of which the present invention does not teach that targeting *H. pylori* for treatment will effectively treat the many diseases that *H. pylori* is involved in.

Further, a review article by Malfertheiner et al. (Aliment Pharmacol Ther 2002; 16: 167-180) points out therapies for the management of *H. pylori*. Beginning on page 173, Malfertheiner et al. discuss therapies and management which include proton pump inhibitors and ranitidine bismuth, among other treatment regimens. However, there is no mention of treatment with pleuromutilins. Therefore, there is no indication that the various types of pleuromutilins that are available will effectively treat diseases associated with *H. pylori*.

**4) The quantity of experimentation necessary:** "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed Cir. 1993)". Undue experimentation would be required in order to practice Applicant's invention because there are no examples provided in the specification. One would have to determine a useful model that correlates with clinical efficacy, a dosage range would

need to be determined as well as a route of administration. Further, if any of the above failed, then the artisan would have to start over again in an effort to determine the suitable methods, dosage ranges and routes of administration in which to determine if the compounds will work to treat all diseases associated with H. pylori.

### ***Conclusion***

No claims are allowed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/  
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